REMARKS

This amendment responds to the Office Action mailed March 29, 2004, for the application identified above. Claims 1 and 7-12 have been cancelled, without prejudice. Claim 1 has been replaced by claim 19, and claims 2, 4 and 5 have been amended to depend from claim 19. Claims 19, 2-6 and 13 -18 remain in the application. Claims 13-18 have been allowed.

Claim 1 was rejected under 35 U.S.C. § 102 as having subject matter that is anticipated by both the Dynasil 4000 Fused Silica lens and the Edmond Optics brochure. Claims 7-12 were rejected under 35 U.S.C. § 103 as having subject matter that is obvious over the combination of the Lai '632 patent and the Dynasil lens.

First, claim 1 has been amended to include features besides the applanation lens that go far beyond merely claiming a new use for a lens formed of silicon dioxide. The claim now includes limitations that establish that the device has features that make the lens specially adapted for use as applanation lens that is held onto the outer surface of the patient's cornea. The lens is sized and shaped to be held in the frame that holds the lens in place, and has an applanation surface that is configured to contact the outer surface of the patient's cornea and provide a reference surface from which the laser is able to compute a depth of focus characteristic. In addition, the lens is formed of high purity synthetic fused silicon dioxide (SiO_2) such that said lens does not discolor or lose light transmittance when subjected to gamma radiation.

These limitations are important and clearly distinguish the claim over the Dynasil 4000 Fused Silica lens and the Edmond Optics brochure which have no disclosure of using a fused silica lens as an applanation lens that is useful for laser surgery on the eye. For example, there is no disclosure in these references of a frame for holding the lens onto the outer surface of a patient's cornea, the lens sized and shaped to be held in the frame or being configured to contact the outer surface of the patient's cornea and provide a reference surface from which the laser is able to compute a depth of focus characteristic.

It is therefore submitted that claim 19 (and dependent claims 2-6) are patentable over the Dynasil 4000 Fused Silica lens and the Edmond Optics brochure.

It is also submitted that claim 19 is patentable over the combination of Lai '632 and the Dynasil lens. Although Lai '632 teaches the use of a frame for holding a lens onto the outer surface of the cornea, having a lens that is sized and shaped to be held in the frame or configured to contact the outer surface of the patient's cornea and provide a reference surface from which the laser is able to compute a depth of focus characteristic, that is where the similarity ends.

Contrary to the Examiner's comment that Lai '632 "fails to teach the material in which the applanation lens is made of," Lai '632 states that "[t]he applanator plate 111 is preferably constructed of a transparent light weight plastic, such as acrylic." ('632 patent, col. 7, lns. 48-50). Thus, the '632 Lai patent teaches away from using an applanator lens formed of fused silica.

Neither is there any teaching or suggestion in the combination of references that a fused silica lens would not discolor when subjected to gamma radiation, which is an important requirement of the applanation lens of claim 19.

Because of these fundamental differences between the cited references and the device in claim 1, is improper to combine these references in support of a rejection based on obviousness. Even if these references could properly be combined, the combination falls short of teaching that a fused silica lens would not discolor if it was sterilized by using gamma radiation.

Even if a prima facie case of obviousness had been established by the Examiner, this has been overcome by the substantial evidence that the claimed invention satisfied a long felt need and produced unexpected results. *See Gillette Co. v. S.C. Johnson & Son, Inc.*, 919 F.2d 720, 725 (Fed. Cir. 1990); *Hybritech Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 231 USPQ 81 (Fed. Cir. 1986) (The claimed invention unexpectedly solved longstanding problems supported the conclusion of nonobviousness). This evidence is in the form of the declaration of Scott Scholler, one of the inventors for the above-identified application, that was

submitted with the amendment filed on February 25, 2004. A copy of Mr. Scholler's declaration is attached hereto as Exhibit A.

Mr. Scholler described that IntraLase Corp, the company that owns the application identified above and is a licensee under the Lai '632 patent, manufactures and sells to ophthalmic surgeons a laser system that is used to form a flap in corneal tissue for the first step in the procedure known as *laser in situ keratomileusis* (LASIK). The surgeon creates the flap using laser energy in a precisely controlled way to photodisrupt tissue below the surface of the cornea. The flap is held by an instrument and lifted to expose underlying internal corneal tissue to be shaped by another laser. Afterward, the flap is returned to its original position. This procedure changes the refractive characteristics of the eye to improve the patient's vision. (Scholler Decl., ¶ 3).

One component for success of this operation is a patient interface device, which stabilizes the patient's eye and holds the laser system in a fixed position relative to the patient's eye. The patient interface holds the laser system in place relative to the eye so that the laser can form the flap at precisely the right location and depth. When coupled to the laser system, a critical part of the patient interface is an applanation lens that contacts the eye. (Scholler Decl., ¶ 4).

The applanation lens must be biocompatible because it contacts the eye, and cannot be formed of a material or create by-products of a material that could irritate or damage the sensitive corneal tissue. The lens must also be sterilized, preferably with gamma radiation. Gamma radiation is preferred to other acceptable methods of sterilization because it lends itself to process controls that result in reduced within-process variability thereby producing higher repeatability from one sterilization run to another. Also, compared with other methods, sterilization by gamma radiation leaves no undesirable residue and is more cost effective. The lens must also be formed of a transparent material, have a high level of transmittance for light in the ranges used by lasers, from UV to IR. The lens material must also be able to transmit the laser light without melting or sputtering to create by-products that would injure eye tissue. (Scholler Decl., ¶ 5).

Mr. Scholler also described the process that he and the other inventors went through in developing a commercial application of the system in the Lai '632 patent, before they discovered that high purity, noncrystalline fused silica was the ideal material for the applanation lens in the patient interface.

Mr. Scholler and his team began by testing plastics of the type described in the Lai '632 patent, which had previously been used in other types of eye products. (See, Lai '632, col. 7, lns. 47-49, which states that "[t]he applanator plate 111 is preferably constructed of a transparent light weight plastic, such as acrylic.") After testing a number of plastic materials, Mr. Scholler's team found that none of them was satisfactory because they either melted or sputtered when laser energy was transmitted through the lens. This effect was unacceptable because the sputtered or melted plastic could injure the eye or cause scarring. (Scholler Decl., ¶ 6).

Mr. Scholler's team next decided to test an optical boron glass material that appeared to be promising because it was biocompatible, had a high degree of transmittance, and would not melt or sputter too much when subjected to laser energy. This material worked well in initial tests. However, when it was sterilized by exposure to gamma radiation it unexpectedly discolored and lost about 20% of its ability to transmit light at the wavelength used in our laser system. (Scholler Decl., ¶ 7).

They then looked for a biocompatible material that would not sputter unacceptably or melt, one that had a high degree of transmittance for laser light, and, when exposed to gamma radiation, would not lose transmittance at the wavelength at which the IntraLase laser operates. The team looked at various types of silica and found that crystalline forms of silica like those used in making glass would also discolor and lose transmittance, but that an amorphous, noncrystalline, synthetic silicon dioxide, called synthetic fused silica, would not discolor when exposed to gamma radiation. This material was tried and found to work. It did not discolor or result in lower transmittance after being sterilized with gamma radiation. (Scholler Decl., ¶ 8). This material is disclosed in the specification on p. 12, ¶ 0047.

This is the product being made and sold by IntraLase, and which is the subject of the claims pending in this application.

Thus, the difficulties in finding a suitable material for the applanator lens and the surprising lack of discoloration after finding Boron glass did discolor, are sufficient to overcome any prima facie case of obviousness that the Examiner might have established by combining Lai '632 and the Dynasil lens or Edmond Optics brochure.

Conclusion

For these reasons it is submitted that the references cited by the Examiner do not render the claimed subject matter obvious and that the pending claims should be allowed. Applicant requests reconsideration and withdrawal of all rejections.

In view of the above, each of the presently pending claims in this application is believed to be in immediate condition for allowance. Accordingly, the Examiner is respectfully requested to pass this application to issue.

Applicant believes no fee is due with this response. However, if a fee is due, please charge our Deposit Account No. 06-2375, under Order No. HO-P02540US1 from which the undersigned is authorized to draw.

Dated: August 2, 2004

Respectfully submitted,

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